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| 10/659,278 | 09/11/2003 | William J. Carroll | 000309-00049 | 5691 |

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BLANK ROME LLP
600 NEW HAMPSHIRE AVENUE, N.W.
WASHINGTON, DC 20037

| EXAMINER | |
|---|---|
| MANUEL, GEORGE C | |
| ART UNIT | PAPER NUMBER |
| 3762 | |
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| 11/19/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/659,278 | CARROLL ET AL. | |
| | Examiner | Art Unit | |
| | George Manuel | 3762 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *19 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *39-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 39, 40 and 43 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by McGraw et al (US 6,393,328).

McGraw et al clearly suggest that "the electrical stimulation is adapted to mimic a sequencing of at least two muscle groups proximate to the body segment and is sufficient to achieve forceful contraction of the at least two muscle groups." For example, col. 6, lines 17-21, teach in a pulsed muscle stimulation mode the electro-medical device 10 generates an alternating biphasic asymmetric balanced pulse pattern. Col. 5, lines 29-33, suggest the portable electro-medical device 10 provides channels that are capable of treating four separate muscle groups. Col. 6, lines 35-39 teach a train of repeating pulses is created during a contract cycle and no pulses are created during a relax cycle. Contract cycles and relax cycles are repeated until an end of treatment.

2. Claims 39-42 and 45-46 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,083,712 ("Keegan, Jr.").

Keegan, Jr. teaches a device for producing transcutaneous electrical muscle therapy. Figure 1 illustrates that at least two electrodes are secured to a body segment (electrode 13 and 17 are illustrated as attached to a leg 11 of a patient. Figure 1 illustrates electrode 13 above the knee, or at the patient's thigh, and electrode 17 below the knee such that the electrodes are proximate the knee of the patient, which is necessarily a joint having a synovium). The device produces sequential programming of synthetic exterior muscle stimulation (see col. 1, lines 55-56), wherein such programmed stimulation is between antagonistic muscles in a proper time relation required for normal function of the muscles (see col. 1, line 70 - col. 2, line 2). Examiner considers such sequential programming "to mimic a sequencing of at least two muscle groups proximate to the body segment" since such stimulation sequence includes a proper time relation required for normal function of the muscles. The electrical stimulation sequencing is believed to provide a movement pattern close to the movement pattern of a normal function muscle, and presents an opportunity for retraining and muscle re-education (see col. 5, line 67 - col. 6, line 3).

With respect to claims 41-42, Keegan, Jr. discloses that the electrical therapy stimulates the nerve and associated muscle (see col. 3, lines 10-12), and thus necessarily provides neuromuscular electrical stimulation.

3. Claims 39-42 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,165,750 ("Aleev et al.").

Aleev et al. discloses a bioelectrically controlled electric stimulation in which the sequence of the electrical stimulation corresponds to the sequence of contractions of muscles in natural conditions (see col. 1, lines 30-45). Examiner considers such sequential programming "to mimic a sequencing of at least two muscle groups proximate to the body segment" since such stimulation sequence corresponds to the sequence of contractions of muscles in natural conditions. Such stimulation is believed to restore the strength of damaged muscles and also restores lost motor skills for enabling a person to perform compound motions of the extremities, torso, and head (see col. 1, lines 25-30 and 40-45). The electric stimulator utilizes an activity sensor (2) which includes two electrodes (3) attached to a first person's skin proximate to muscles for obtaining the bioelectric activity of muscles of a person who sets a program of movements (see col. 7, 30-40 and Figure 1; see also col. 11, lines 23-35). Such program of movements is used to stimulate the muscles of a second person under control via two electrodes 19 (see col. 8, lines 15-25 and Figure 1; see also col. 11, line 62 - col. 12, line 33).

With respect to claims 41-42, the electrical stimulation of Aleev et al. causes the muscles to be excited and contract, and thus necessarily provides neuromuscular electrical stimulation (see, as evidence, U.S. Patent No. 5,070,873 at col. 1, lines 23-30 which describes that muscle fibers contract in response to the electrical stimulation of neural motor units).

4. Claims 39-42 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,350,415 ("Cywinski").

Cywinski discloses a method for the electrostimulation of muscles, which electronically synthesizes the stimulus firing patterns to be similar to that of recorded, natural Motor Unit Action Potentials (or MUAPs), which are electrical discharges in individual groups of muscle cells which contract together, in order to provide functional and structural trophic changes in the muscle (see col. 3, lines 8 - 69). Such an electrical stimulation pattern is applied to a body segment via stimulating electrode means (3), which includes at least two electrodes as shown in Figures 3, 5, and 7. Examiner considers electrical stimulation "adapted to mimic a sequencing of at least two muscle groups proximate to the body segment" to encompass the electrical stimulation disclosed in Cywinski which is adapted to emulate the natural MUAPs because such MUAPs are naturally-occurring electrical discharges of a muscle group.

With respect to claims 41-42, Cywinski discloses that the device is a neuromuscular stimulator (see col. 3, line 25-26).

### *Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 3,083,712 ("Keegan, Jr.").

Keegan, Jr. fails to explicitly disclose applying the electrical stimulation for approximately ten minutes to approximately four hours. Keegan. Jr. teaches that the time interval for stimulation is controlled by capacitor 69 (see col. 4, lines 50-57), which is programmed in accordance with normal muscle function. Further, Keegan, Jr. teaches that it is important to for the muscle to get enough stimulation to work the muscle without over stimulation which would cause discomfort and muscle fatigue (see col. 3, lines 69-73). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the method of Keegan, Jr. such that the treatment time is between ten minutes to four hours in order to work the muscle without over stimulation which would cause discomfort and muscle fatigue. Examiner notes that it has been held that discovering an optimum value of a result effective variable (such as, in this case, the time for electrical stimulation treatment) involves only routine skill in the art. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

7. Claims 39, 43, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,324,317 ("Reiss") in view of U.S. Patent No. 3,083,712 ("Keegan, Jr.").

Reiss discloses a portable inferential stimulator for producing a low frequency therapeutic current at a selected point in order to reduce pain, reduce edema and inflammation, increase blood flow, and reduce muscle spasms (see Abstract). Reiss

discloses that the inferential stimulator includes a mode control to permit changing the sequence of stimulation to find the most effective pain relief (see col. 1, line 62 - col. 2, line 16). Reiss fails to specifically disclose a mode of operation in which the electrical stimulation is applied having characteristics and sequencing which mimic normal electrical sequencing of surrounding muscles of the joint during normal functioning activity. Keegan, Jr. teaches a device for producing transcutaneous electrical muscle therapy which produces sequential programming of synthetic exterior muscle stimulation, wherein such programmed stimulation is between antagonistic muscles in a proper time relation required for normal function of the muscles (see col. 1, line 70 - col. 2, line 2). The electrical stimulation sequencing is believed to provide a movement pattern close to the movement pattern of a normal function muscle, and presents an opportunity for retraining and muscle re-education (see col. 5, line 67 - col. 6, line 3). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the sequence of stimulation of the inferential stimulator disclosed in Reiss such that the sequence of stimulation mimics normal electrical sequencing of surrounding muscles of the joint during normal functioning activity as taught by Keegan, Jr. in order to retrain and re-educate the muscle to take over normal function and control while simultaneously providing pain relief.

With respect to claim 43, Reiss discloses that the electrical stimulation includes a duration from 10 minutes to 4 hours per day (treatments of up to about 60 minutes are preferred; see col. 2, lines 20-26).

With respect to claim 44, Reiss discloses that the electrical stimulation is within a range of 5 mA to 150 mA (the preferable output amperage varies from about 0 to 50 milliamps; see col. 2, lines 18-26).

***Response to Arguments***

8. Applicant's arguments filed 10/19/07 have been fully considered but they are not persuasive.

The device of McGraw et al clearly is capable of achieving a forceful contraction of at least two muscle groups and provides a safety feature to control the forcefulness of the contractions. This safety feature comprises at the start of a treatment, setting a channel output to above zero. This ensures the user will receive a forceful contraction but not so strong as to create an abrupt muscle contraction when starting a treatment.

Further, the device of McGraw et al is adapted to mimic a sequencing of muscle groups to provide the following treatments: the relaxation of muscle spasms, the prevention or retardation of muscle disuse atrophy, increasing local blood circulation in the legs or other limbs of the patient, reeducating the leg muscles or other muscles of the patient, providing immediate post-surgical stimulation of calf muscles of the patient in order to prevent venous thrombosis, maintaining or increasing the range of motions of the patient's legs or other limbs.

Applicant's argument that there is nothing in Keegan, Aleev nor Cywinski that supports sequential programming "to mimic a sequencing of at least two muscle groups proximate to the body segment" since such stimulation sequence includes a proper time

relation required for normal function of the muscles, is without merit. The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965).

Applicants may argue that the examiner's conclusion of obviousness is based onimproper hindsight reasoning. However, "[a]ny judgement on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." In re McLaughlin 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971). Applicants may also argue that the combination of two or more references is "hindsight" because "express" motivation to combine the references is lacking. However, there is no requirement that an "express, written motivation to combine must appear in prior art references before a finding of obviousness." See Ruiz v. A.B. Chance Co., 357 F.3d 1270, 1276, 69 USPQ2d 1686, 1690 (Fed. Cir. 2004). For example, motivation to combine prior art references may exist in the nature of the problem to be solved (Ruiz at 1276, 69 USPQ2d at 1690) or the knowledge of one of ordinary skill in the art (National Steel Car v. Canadian Pacific Railway Ltd., 357 F.3d 1319, 1338, 69 USPQ2d 1641, 1656 (Fed. Cir. 2004)).

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Manuel whose telephone number is 571-272-4952. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George Manuel/
Primary Examiner
Art Unit 3762